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L6: Entry 3 of 14 File: USPT Jul 31, 2001

US-PAT-NO: 6267986
DOCUMENT-IDENTIFIER: US 6267986 B1

TITLE: Process for the preparation of a controlled drug delivery system containing pseudoephedrine and a long acting antihistamine

DATE-ISSUED: July 31, 2001

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
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Sen; Himadri	Gurgaon			IN

US-CL-CURRENT: 424/472; 424/468, 424/469, 424/470, 424/474, 514/770, 514/779, 514/781, 514/782

CLAIMS:

We claim:

1. A process for the preparation of a pharmaceutical composition in the form of a tablet comprising two discrete zones wherein the first zone is formed by mixing a therapeutically effective amount of pseudoephedrine or its pharmaceutically effective salt, one or more hydrophilic polymer(s), a salt of a polyuronic acid and a pharmaceutically acceptable salt of a group II metal ion and tableting the blend so obtained; wherein the second discrete zone is formed by mixing a therapeutically effective amount of a long-acting antihistamine selected from the group consisting of loratadine, azatadine, fexofenadine, terfenadine, cetirizine, astemizole, and levocabastine or their pharmaceutically acceptable salt with at least one pharmaceutically acceptable excipient, and optionally converting the blend into granules and either (a) compressing the blend or the granules onto the first discrete zone or (b) coating the blend onto the first discrete zone with the aid of a binder solution.

2. A process as claimed in claim 1 wherein the hydrophilic polymers are selected from the class of cellulose ethers.

3. A process as claimed in claim 2 wherein the cellulose ether is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, and mixtures thereof.

4. A process as claimed in claim 3 wherein the hydroxypropyl methylcellulose is such that it's 2% by weight aqueous solution has a viscosity greater than 10,000 cPs and the hydroxypropylcellulose is such that it's 2% by weight aqueous solution has a viscosity less than 5,000 cPs.

5. A process as claimed in claim 1 wherein the hydrophilic polymer is xanthan gum.

6. A process as claimed in claim 1 wherein the salt of a polyuronic acid is calcium alginate.

7. A process as claimed in claim 1 wherein the salt of a polyuronic acid is sodium alginate.

8. A process as claimed in claim 1 wherein the salt of a polyuronic acid is sodium calcium alginate.

9. A process as claimed in claim 1 wherein the salt of a group II metal ion is calcium carbonate.

10. A pharmaceutical composition in the form of a tablet comprising two discrete zones; wherein the first zone comprises a therapeutically effective amount of pseudoephedrine or its pharmaceutically effective salt, one or more hydrophilic polymer(s), a salt of a polyuronic acid and a pharmaceutically acceptable salt of a group II metal ion; wherein the second discrete zone comprises an effective amount of a long-acting antihistamine selected from the group consisting of loratadine, azatadine, fexofenadine, terfenadine, cetirizine, astemizole, and levocabastine or their pharmaceutically acceptable salt with at least one pharmaceutically acceptable excipient.

11. The composition as claimed in claim 10 wherein the hydrophilic polymers are selected from the class of cellulose ethers.

12. The composition as claimed in claim 11 wherein the cellulose ether is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, and mixtures thereof.

13. The composition as claimed in claim 12 wherein the hydroxypropylmethylcellulose is such that it's 2% by weight aqueous solution has a viscosity greater than 10,000 cPs and the hydroxypropylcellulose is such that it's 2% by weight aqueous solution has a viscosity less than 5,000 cPs.

14. The composition as claimed in claim 10 wherein the hydrophilic polymer is xanthan gum.

15. The composition as claimed in claim 10 wherein the salt of a polyuronic acid is calcium alginate.

16. The composition as claimed in claim 10 wherein the salt of a polyuronic acid is sodium alginate.

17. The composition as claimed in claim 10 wherein the salt of a polyuronic acid is sodium calcium alginate.

18. The composition as claimed in claim 10 wherein the salt of a group II metal ion is calcium carbonate.

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Rampal; Ashok	Gurgaon			IN
Sen; Himadri	Gurgaon			IN

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
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FIELD-OF-SEARCH: 424/468, 424/472, 424/465, 424/469, 424/470, 424/473, 424/474, 424/479, 424/480

PRIOR-ART-DISCLOSED:

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Search Selected | Search ALL

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☐	3326924	June 1967	Uspo	
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☐	3878217	April 1975	Carr et al.	
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☐	4369184	January 1983	Stokbroekx et al.	
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☐	4990535	February 1991	Cho et al.	514/556
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9409761	May 1994	WO	
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ART-UNIT: 165

PRIMARY-EXAMINER: Spear; James M.

ABSTRACT:

This invention relates to a process for the preparation of a controlled release pharmaceutical composition comprising two discrete zones wherein the first discrete zone comprises therapeutically effective amount of pseudoephedrine or its pharmaceutically acceptable salt as active ingredient and the second discrete zone comprises a therapeutically effective amount of a long-acting antihistamine selected from the group consisting of loratadine, azatidine, fexofenadine, terfenadine, cetirizine, astemizole, and levocabastine, or their pharmaceutically acceptable salt as active ingredient.

18 Claims, 0 Drawing figures